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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,206	06/26/2001	Nigel D. Atherton	20342/0202324-US0	9337

7278 7590 07/05/2005

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/891,206	ATHERTON ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005 and 09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-19,23,24,26-32,34-47 and 49-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,8-19,23,24,26-32,34-47 and 49-55* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

→ New reference cited to further show the state of the art.

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 06302005
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/2005 has been entered.

All amendments filed on 6/9/2005 have been considered. No new matter is found in said amendments.

The amendment filed on 4/27/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: deletion of lines 27-28 on specification page 43 (original line numbering).

The amendment of 4/27/2005 deletes "Incorporation of lanthanum within bone (modified solochrome azurine technique)" at specification page 43, lines 27-28. The originally filed disclosure stated that specimens taken from the iliac crest of growing immature dogs were analyzed for incorporation of lanthanum within bone (via modified solochrome azurine technique) after being orally treated with 1000 mg/kg of lanthanum carbonate twice daily for 13 weeks.

Applicant now states that this was an inadvertent error made without deceptive intent (Remarks of 4/27/2005). Applicant states that although it was believed at the time of the originally filed disclosure that the solochrome azurine technique had the sensitivity to detect lanthanum in bone, it was later determined that this technique "did not have the sensitivity required to detect lanthanum incorporation into the bone of animals orally dosed with lanthanum."

35 USC 132(a) requires that "No amendment shall introduce new matter into the disclosure of the invention." In Chen v. Bouchard, 68 USPQ2d 1705 (Fed. Cir. 2003), the court held, in the context of granting benefit of an earlier filing date, correcting an erroneous disclosure gave rise to new matter (hence no benefit of earlier date) even though the correction was inherently disclosed in the originally filed disclosure. Similarly here, the correction of a supposedly erroneous disclosure that is inherently incorrect gives rise to new matter. The court in Chen determined that it is new matter when the added disclosure "would *not* have been recognized by a person of ordinary skill in the art" at the time of the original filing date. Id. at 1711 (emphasis in the original). Here, as discussed in the preceding paragraph in this Office action, applicant *admits* that the ordinary skilled artisan would have accepted applicant's original disclosure – put another way, applicant admits that the ordinary skilled artisan would not have recognized an obvious error in applicant's disclosure on specification page 43, lines 27-28 at the time the invention was originally filed.

Consequently, the deletion of lines 27-28 on page 43 is deemed to be new matter, which cannot be permitted under 35 USC 132.

The Examiner believes that applicant has met the burden of providing a full accounting of how the error arose. Unfortunately, it appears that the error cannot be corrected short of filing a CIP application. However, the Examiner makes the following observations for the record:

(1) It is not disputed that incorporation of lanthanum within bone was in fact attempted to be measured by the modified solochrome azurine technique. Therefore, specification page 43, lines 27-28 does not in fact contain any error.

(2) What applicant believes as "error" is based on the subsequent understanding that the technique was actually not sensitive enough to detect lanthanum incorporation in applicant's tests. Thus, the asserted error would not have been obvious to the ordinary skilled artisan.

(3) Therefore, deletion of specification page 43, lines 27-28 would actually do more than correct an obvious error. First, the error was not obvious, as admitted by applicant. Second, the deletion would change the disclosure since it would no longer disclose the test that applicant actually did use to measure lanthanum incorporation within bone. Consequently, applicant's amendment with respect to specification page 43, lines 27-28 cannot be permitted.

Applicant is required to cancel the new matter in the reply to this Office Action.

Allowance of claims remains unchanged. All presently pending claims are allowed again.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner Pak informed Ms. Fujikawa that the amendment to specification page 43, wherein oringal lines numbered 27-28 are deleted, would constitute new matter Ms. Fujikawa asked if in response to an Office action said amendment were withdrawn (i.e. original disclosure restored), would the claims still be deemed allowable. The Examiner replied that the claims are still deemed to be allowable at this time. At the time of the next Office action, the claims would be subject to another search update.